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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,280	12/12/2003	Tom Tsang	246392US20CONT	8225
22850	7590	05/02/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			PRIEBE, SCOTT DAVID	
			ART UNIT	PAPER NUMBER

1633

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/733,280	<b>Applicant(s)</b> TSANG ET AL.	
	<b>Examiner</b> Scott D. Priebe, Ph.D.	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 47-70 is/are pending in the application.  
     4a) Of the above claim(s) 59-70 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-57 is/are allowed.
- 6) ☒ Claim(s) 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Newly submitted claims 59-70 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The originally presented invention and the newly presented invention are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the newly presented invention is not embraced by the originally presented claims, and there is no evidence of record that they are obvious variants of one another. The originally presented and newly presented inventions have a materially different design, since the original invention requires an HIV-2 promoter and coding sequence for a tat protein active on the HIV-2 promoter, not the HIV-1 promoter and coding sequence for a tat protein active on the HIV-1 promoter of the newly presented invention. Furthermore, the different expression constructs of the two inventions have different effects, as shown by the results of Table IV. Whereas the original invention has a high constitutive rate of expression that is only modestly increased by induction of the inducible promoter, the newly presented invention has a much lower basal rate of expression, and a substantially increased rate of expression under inducing conditions. Search and examination of the newly presented claims would pose a serious search burden since the

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search of the original invention does not overlap the search required for the newly presented invention, and *vice versa*.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 59-70 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 58 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly presented claim 58 is directed to an embodiment of the invention wherein the inducible promoter is the CMV promoter. Applicant indicates that support for this limitation is found in Table 3 and in Fig. 9 of the instant pacification.

However, Table 3 only shows that applicant was in possession of an amplifier construct wherein the CMV promoter is operably linked to the HIV tat coding sequence. It does not suggest that Applicant had contemplated this embodiment as being part of the invention now being claimed where an inducible promoter directs expression of the HIV tat. At page 13, line 4,

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and page 62, lines 24-26, the CMV is characterized as a “constitutive” promoter, and explicitly not a heat-shock inducible promoter. At page 62, lines 15-16, the specification teaches that “CMV promoter activity is essentially unaffected by temperature in these cells” when operably linked to an EGF coding sequence. The results in Table 4 clearly show that expression of IL-2 under control of the CMV promoter (the L-27 construct, Table 3) was not statistically different at any of the temperatures employed in the assay. If anything, expression from the CMV promoter was reduced at higher temperature. Thus, from these teachings in the original specification one of skill in the art would clearly have had no reason to believe that the CMV promoter was an inducible promoter or that Applicant had contemplated it as being an inducible promoter. Consequently, the original specification provides evidence that Applicant did not contemplate amplifier constructs comprising the CMV promoter to embodiments of the invention now being claimed that require an inducible promoter. The Dammeyer exhibit has been considered, but it is not dispositive in this situation, where the evidence from the original specification clearly indicates that the embodiment involving the CMV promoter was not considered to be embraced by the instantly claimed invention requiring an inducible promoter.

### ***Double Patenting***

The terminal disclaimer filed on 3/22/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 6,709,858 or any patent issuing from allowed U.S. Appl. Nos. 10/108,486 and 10/152,577 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Conclusion***

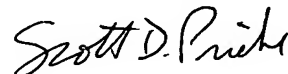
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.  
Primary Examiner  
Art Unit 1633